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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,843	03/30/2001	Samir Kumar Brahmachari	Q63915	7045

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WASHINGTON, DC 20037-3213

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

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08/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/820,843	Applicant(s) BRAHMACHARI ET AL.	
	Examiner Carolyn L. Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007 and 22 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,22-24 and 26-29 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendments and remarks, filed 7/10/07 and 3/22/07, are acknowledged.

Amended claims 20 and 26-28 and cancelled claims 1-19, 21, 25, and 30-33 are acknowledged.

Applicants' arguments, filed 7/10/07 and 3/22/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 20, 22-24, and 26-29 are herein under examination.

Claim Objections

Claim 20 is objected to because of the following informalities: Claim 20, lines 16 and 17, recite the limitation "proteins sequences" which is syntactically awkward. Appropriate correction is required. This objection is necessitated by amendment.

Claim Rejections – 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and

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reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 20, 22-24, and 26-29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention. This rejection is necessitated by amendment.

Claim 20 begins with calculating protein-sequence based attributes from protein sequences of a pathogenic organism (step a), clustering said protein sequences from this particular pathogenic organism (step b), identifying outliers from this particular pathogenic organism (step c), and then comparing said outlier protein sequences of a specific group of pathogenic organisms “to identify outlier proteins that are unique to said pathogenic organism” which lacks enablement. One skilled in the art would not know how to get from the first three steps which deal with a particular pathogenic organism and then compare outlier protein sequences of the select group of pathogenic organisms “to identify outlier proteins that are unique to said pathogenic organism”. Step d) of instant claim 20 recites comparing said outlier

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protein sequences of a group of pathogenic organisms, but does not state to what they are being compared. Are they compared to the outlier protein sequences of the pathogenic organism recited in step a)? Step d) identifies outlier proteins that are unique to said pathogenic organism; however, the sequences of the organism are not necessarily being compared in the recited “said outlier protein sequences” that are now amended to be from a group consisting of 16 organisms. Merely comparing sequences would not necessarily lead one skilled in the art to determination that the outlier proteins are unique. For example, if one compared the sequences to a National Center for Biotechnology Information (NCBI) database and there are no identical matches, it could be that the sequence does exist in another pathogenic organism, but it hasn’t been sequenced yet. It is possible that another pathogenic organism has the sequence but it is rarely expressed and various other scenarios. Or the unique outlier sequence may have matches to ESTs at any particular percent homology when in fact the sequence is truly unique to that particular pathogenic organism. One skilled in the art would need to know at what point something is unique to the organism as opposed to being unique to the genus.

Due to the large quantity of experimentation necessary to determine that the outlier proteins are truly unique to the pathogenic organism, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, and the breadth of the claims which fail to recite how to scientifically conclude that the proteins are unique to the pathogenic organism, the specification fails to teach the skilled artisan how to use the claimed invention. Claims 22-24 and 26-29 are also rejected due to their dependency from claim 20.

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Applicants argue they have overcome the rejection by amending claim 20 to include the pathogenic organisms tested and the databases of protein sequences to the organisms and the databases of organisms. This statement is found unpersuasive as not all of these limitations are clearly stated in claim 20, as discussed above.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 22-24, and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20, step (a) recites “wherein said protein sequences are predicted from either whole genomic sequences, or from partial genomic sequences comprising at least one chromosome” which is vague and indefinite. It is unclear what comprises at least one chromosome. One skilled in the art would consider “partial genomic sequences comprising at least one chromosome” to be nonsensical. A chromosome may comprise whole genomic sequences or a partial genomic sequence, but not the other way around. It is unclear if Applicants intend to mean that the partial genomic sequences are selected from at least one chromosome or some other scenario. Clarification of this issue via clearer claim wording is requested. Claims 22-24 and 26-29 are also rejected due to their dependency from claim 20. This rejection is maintained.

Applicants argue that a genome can constitute more than one chromosome, whereas a gene would not. This statement is found unpersuasive as claim 20 does not recite a genome or gene, but rather “whole genomic sequences”, “partial genomic sequences”, and “chromosome” that still have the issues addressed above.

Claim 20 recites “comparing said outlier protein sequences of a group of pathogenic organisms” which lacks clear antecedent basis and is confusing. The outlier protein sequences previously recited in the claim are from one pathogenic organism, not a group as now recited. It is also unclear to what these outlier protein sequences are being compared. If applicant intends the outlier protein sequences of said pathogenic organism of step a) to be compared to the outlier protein sequences from the group of pathogenic organisms of step d), then step d) must be carefully worded to reflect this limitation. Clarification of this issue via clearer claim wording is requested. Claims 22-24 and 26-29 are also rejected due to their dependency from claim 20. This rejection is necessitated by amendment.

Claim 20 recites the limitation “the databases” in line 23. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of databases. Clarification of this issue via clearer claim wording is requested. This rejection is necessitated by amendment.

Claims 26-28 (line 1) recite “the outlier protein” which lacks clear antecedent basis as these claims refer back to step d) that states identifying multiple “outlier proteins”, not just one. It is unclear to which particular “outlier protein” is being referred in claims 26-28. Clarification of this issue via clearer claim wording is requested. This rejection is necessitated by amendment.

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Claim 28 (line 2) recites "selected in step (e)" which is confusing as step (e) has been amended so that it is no longer recites any sort of selecting. Clarification of this issue via clearer claim wording is requested. This rejection is necessitated by amendment.

Claim 29 limits the method to be a computer-implemented one (i.e. performed by a computer system). However, it is unclear what limitation of the METHOD of claim 20 is intended by the recitation of certain structural elements. Clarification of this issue via clearer claim wording is requested. This rejection is maintained.

Applicants argue that since claim 29 recites "wherein steps (a)-(c) are performed by a computer system comprising," this rejection appears to have no merit. This statement is found unpersuasive as claim 29 recites a wherein clause comprising certain structural elements making it unclear as to what limitation of the method of claim 20 is intended by these structural elements.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

August 13, 2007

/Carolyn Smith/
Primary Examiner
AU 1631